

510(k) SUMMARY

Page 1 of 2

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TRADE NAME: CAVITRON™ JET WITH SPS SYSTEM

CLASSIFICATION NAME: Ultrasonic Scaler 21 CFR, 872.4850

PREDICATE DEVICE: CAVITRON® JET SCALER K864996

DESCRIPTION: The CAVITRON™ JET WITH SPS SYSTEM is a portable stand alone multi-functional prophylaxis unit. It has two operating modes: an ultrasonic scaler mode and an air polishing (JET) mode. The ultrasonic scaler mode operates using a Cavitron® ultrasonic scaling insert with a fine, warm water spray, easily and effectively removing stubborn calculus and stains both supragingivally and subgingivally. The JET mode operates using a Cavitron® JET Air Polishing Insert with an air/powder/water spray, easily removing gross stain and plaque from all exposed tooth surfaces.

The CAVITRON™ JET WITH SPS SYSTEM has six components: electronic generator (contained in a base unit, foot control, handpiece and cable assembly, detachable line cord, DENTSPLY® Cavitron® Ultrasonic Sterilizable Inserts, and Cavitron® JET Air Polishing Inserts.

The CAVITRON™ JET WITH SPS SYSTEM plugs into an ordinary electrical outlet and converts the 60 cycle AC house current into either high frequency electro-mechanical vibrations in the scaling mode, or a spray mixture of air, water and powder in the JET mode. Mode selection occurs automatically when either a Cavitron® ultrasonic sterilizable insert or a Cavitron® JET air polishing insert is placed into the handpiece. The device consists of three parts: an electro-mechanical transducer, an electronic driving system, and an air/powder module. The transducer converts electrical energy in the form of a magnetic field into mechanical motion. The electronic system, in addition to providing the magnetic field, incorporates two control loops, one providing automatic frequency control driving each transducer at it's optimum operating frequency (nominally 30 kHz), while the second loop provides automatic stroke control to compensate for different transducer loading conditions. The air/powder module consists of the automatic selection and control electronics, the pneumatic controls and a powder reservoir. In the scaling mode, the CAVITRON™ JET WITH SPS SYSTEM produces 30,000 microscopically small strokes each second at the transducer's tip. This, combined with acoustic effects of the coolant water, produces a synergistic action that sweeps away the heaviest calculus deposits while providing exceptional operator and patient comfort. In the JET mode, the CAVITRON™ JET WITH SPS SYSTEM produces a spray mixture of air, water and specially processed sodium bicarbonate required for cleaning, polishing and restoring the natural esthetics of tooth enamel.

000031

510(k) SUMMARY (cont'd.)

Page 2 of 2

CAVITRON™ JET WITH SPS SYSTEM

DESCRIPTION (cont'd.): While the controls for the power and water flow of the CAVITRON™ JET WITH SPS SYSTEM are located on the base unit, the on/off control used during operation is located on the foot pedal. When the foot pedal is pressed to the first position, the ultrasonic tip is activated and irrigation starts when in the scaling mode; only water flows when in the JET mode. The water from the irrigation system acts as both a lavage and a coolant.

When the foot pedal is pressed to the second position and the unit is in the scaling mode, power to the handpiece is increased slightly for the length of time the second position is engaged. Irrigation continues to flow. When the unit is in the JET mode, a spray mixture of water, air and powder is generated.

INTENDED USE: The CAVITRON™ JET WITH SPS SYSTEM is designed for use in general prophylaxis and periodontal treatments and other areas of operative dentistry. This CAVITRON™ JET WITH SPS SYSTEM is used to debride light to heavy calculus and plaque deposits from tooth and root surfaces.

TECHNOLOGICAL CHARACTERISTICS: The CAVITRON™ JET WITH SPS SYSTEM is substantially equivalent to the predicate device, DENTSPLY's Cavitron® JET Scaler (K864996), in intended use, as well as in design and construction. The basic technology, primary energy source, maximum electrical input power, maximum input air and water pressure, maximum mechanical output energy, and base unit material are identical to the predicate device.

The CAVITRON™ JET WITH SPS SYSTEM has the following enhancements: 1) a low power capability providing lower tip strokes than previously obtainable for periodontal applications and greater patient comfort; 2) a foot switch activated boost power mode which, when enabled, applies increased power to the handpiece; 3) a limited Automatic Gain Control circuit which automatically increases insert drive power, maintaining tip stroke under load; 4) a smooth or appropriately textured, white base unit capable of withstanding common wipe disinfectants without discoloring or deteriorating; 5) easier access to air filters for maintenance; and 6) an enhanced pinch tube design.

The CAVITRON™ JET WITH SPS SYSTEM meets DENTSPLY Specifications. Underwriters' Laboratory conducted EMC testing on the SYSTEM with positive results.

Results of in-house testing indicated that the CAVITRON™ JET WITH SPS SYSTEM performed within stated specifications and was found to be as effective as the predicate device.

Results of SEM Analysis indicated that no significant qualitative difference was observed on the teeth following the use of the CAVITRON™ JET WITH SPS SYSTEM compared to the predicate device.

We believe that the performance data and the testing reported above demonstrate the safety and effectiveness of the CAVITRON™ JET WITH SPS SYSTEM for its intended use.

000032